Schedule Number: NC1-088-83-03

Some items in this schedule are either obsolete or have been superseded by new NARA approved records schedules. This information is accurate as of: 11/14/2022

ACTIVE ITEMS

These items, unless subsequently superseded, may be used by the agency to disposition records. It is the responsibility of the user to verify the items are still active.

All other items not listed below are active.

SUPERSEDED AND OBSOLETE ITEMS

The remaining items on this schedule may no longer be used to disposition records. They are superseded, obsolete, filing instructions, non-records, or were lined off and not approved at the time of scheduling. References to more recent schedules are provided below as a courtesy. Some items listed here may have been previously annotated on the schedule itself.

Item K-13 is superseded by N1-088-08-001, item 2.1.
Item K-14 is superseded by N1-088-07-002, item 5.2
Item K-18 is superseded by N1-088-08-001, item 2.2.
Item K-19 is superseded by N1-088-08-001, item 2.3.
Items K-20 and K-22 are superseded by N1-088-08-001, item 2.4.
Item K-23 is superseded by N1-088-08-001, item 2.5.
Item K-25 and K-29 are superseded by N1-088-07-002, item 6.1.

REQUEST FOR RECORDS DISPOSITION AUTHORITY
(See Instructions on reverse)

LEAVE BLANK
JOB NO. NC1-88-83-3
DATE RECEIVED 6-28-83
NOTIFICATION TO AGENCY
In accordance with the provisions of 44 U.S.C. 3303a the disposal request, including amendments, is approved except for items that may be stamped "disposal not approved" or "withdrawn" in column 10.
3-1-85 (Date) — Archivist of the United States

TO: **GENERAL SERVICES ADMINISTRATION, NATIONAL ARCHIVES AND RECORDS SERVICE, WASHINGTON, DC 20408**

1. FROM (AGENCY OR ESTABLISHMENT)
Department of Health and Human Services

2. MAJOR SUBDIVISION
Public Health Service

3. MINOR SUBDIVISION
Food and Drug Administration

4. NAME OF PERSON WITH WHOM TO CONFER
Jaquelyn L. Tolson
PHS Records Officer

5. TEL. EXT.
443-2055

6. CERTIFICATE OF AGENCY REPRESENTATIVE:

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposal of the agency's records; that the records proposed for disposal in this Request of 6 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified.

☐ **A** Request for immediate disposal.

☒ **B** Request for disposal after a specified period of time or request for permanent retention.

C. DATE	D. SIGNATURE OF AGENCY REPRESENTATIVE	E. TITLE
6/20/83	Dr. George E. Deal	DHHS Records Officer

7. ITEM NO.	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO.	10. ACTION TAKEN
	This request is for a change to the FDA Records Control Schedule approved on February 23, 1978 (NARS job no. NC 1-88-78-1). This change updates the medical device record items in the present schedule by incorporating new files established since the approval date, deleting those no longer required, reducing retention periods when possible and as requested by NARS, and revising file titles and descriptions as necessary.		
K-1	Deleted		
K-2	Deleted		
K-3	Deleted		
K-4	Deleted		
K-5	Establishment Inspection Reports (devices only) Inspection forms, summary reports, findings, recommendations, and related correspondence concerning the inspection of medical device producers' facilities to determine if they comply with Good Manufacturing Practices (GMPs). Also used for program requirements and evaluations. Transfer to appropiate AF jacket (see item A2-1) 2 years after receipt. FDA Records Officer — 5/25/83 (Date) — 443-4055 (Telephone)	RCS/10331/ K5	19 items

115-107 To agency
NC, NNF, NNB
6 Mar 85

STANDARD FORM 115
Revised April, 1975
Prescribed by General Services Administration
FPMR (41 CFR) 101-11.4

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
K-6	Deleted		
K-7	Deleted		
K-8	Deleted		
K-9	Deleted		
K-10	Deleted (replaced by item K-22, below)		
K-11	Form 2687 File Copies of form FDA 2687, Notification of Shipment of In Vitro Diagnostic Product for Investigational Use, submitted by producers. Cutoff file at end of each year. Transfer to Federal Records Center (FRC) 5 years after cutoff. Destroy 10 years after cutoff.	RCS/B331/ K11 No Change	
K-12	Submission for Standards Equipment diagrams, production methods, quality controls, inspections for use, etc. gathered by FDA from producers, laboratories, and professional and consumer groups. The information so obtained is used to develop medical device safety and performance standards. a. Original material Transfer to FRC when product standard is put into effect. Destroy 30 years after product standard has been put into effect. b. Copies Destroy after 1 year unless needed for further use.	RCS/B331/ K12	
K-13	Classification and Reclassification Petition File Documents relating to and supporting the classification and reclassification of medical devices. Used to (1) track progress of FDA Advisory Panels, (2) assess the number and types of devices in the classification categories, (3) respond to inquiries from the public regarding specific classifications, and (4) help in establishing priority ranking for device standard development. a. Classification files Transfer to FRC 10 years after classification action is completed. Destroy 30 years after action completed. Amended by Linda Henry, NCO Per Fred Sadler 14Aug84	RCS/B331/ K13	

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
	b. Reclassification Petitions Transfer to FRC 10 years after ~~petition is received.~~ action is completed Destroy 20 years after action is completed. Amended by Linda Henry, MD per Fred Sadler 4/4/89		
K-14	Device Experience Network Reports Copies of form FDA 2519f, Medical Device and Laboratory Product Problem..., received from U.S. Pharmocopeia and others regarding problems associated with device adverse experiences. Transfer to FRC 3 years after date of receipt. Destroy 8 years after receipt.	RCS/8331/ K 14	8 years
K-15	National and International Standards Survey (ADP) System maintains medical device standard development information. Used to produce the National Center for Devices and Radiological Health Standards Survey. Destroy (erase) individual data as they become inactive or are updated.	RCS/8331/ K 15 & K 16	
K-16	Deleted (combined with item K-15, above)		
~~K-17~~	~~Document Control (ADP)~~ ~~System maintains a file of data from producers. Used to track and maintain a history of correspondence submitted to meet legal requirements.~~ ~~Destroy individual data as they become inactive.~~	RCS/8331/ K 17 NO CHANGE	
K-18	Classification Requirements of the MDA Information Requests Reports and Agency responses as to which class a device has been assigned and the requirements of Section 513(g) of the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act (MDA) applicable to the device. Transfer to FRC 5 years after action completed. Destroy 25 years after action completed.		
K-19	Investigational Device Exemptions (IDEs) Applications from producers and others to test medical devices for safety and efficacy prior to marketing. Also, FDA evaluations and approval decisions with supporting material made under Section 520(g) of the MDAs.		

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
Amended by RLHain, NIH, per Memo of 3Oct84 from J.W. Anderson.	a. Paper 1 Original ~~Transfer to FRC 5 years after approval decision is made. Destroy 25 years after approval decision is made.~~ Destroy on verification of microfiche. b. Microfiche 1 Copies Transfer to FRC 5 years after Final action. Destroy ~~not later than 30~~ years after ~~approval decision is made.~~ Final action.		
K-20	Premarket Approvals (PMAs) Applications from producers and other initiators for approval to market Class III products including, but not limited to, clinical data; test results; amendments; supplements; labeling; promotional material; progress reports; adverse reactions; FDA evaluations; approvals, disapprovals, and withdrawals; and related correspondence and other material. The information in this file is used to determine the safety and effectiveness of medical devices. Transfer to FRC 5 years after last action taken. Destroy 30 years after last action taken.		
~~K-21~~	Product Development Protocols Correspondence, supporting data, and other material related to the development, submission, approval, denial, or other action required under Section 515(f) of the MDAs. Transfer to FRC 5 years after last action taken. Destroy 30 years after last action taken.		WITHDRAWN by Linda Henry, NIH per Fred Sadler 14Aug84
K-22	Transitional Devices Applications and related documents ("forms 5s and 6s" and Batch Certifications) to test and market devices, including biologicals and antibiolotical, received and processed as INDs/NDAs (see items D-5 and D-6) prior to enactment of the MDAs. Processed under provisions of Section 520(1) of the MDAs. Transfer to FRC 5 years after last action taken. Destroy 25 years after last action taken.	RLS/0991/ K 10	
K-23	Premarket Notifications Correspondence and other documents received from persons and manufacturers seeking to introduce a medical device on the market that is substantially equivalent to an already approved device. Also, FDA evaluations and approval decisions made under Section 510(k) of the MDAs.		

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
Amended by DAlvin, NIR, per Memo of 9 Oct 84 from J. W. Anderson.	a. Paper Original Destroy on verification of microfiche. ~~Transfer to FRC when approval decision made and microfilm copies made of key documents. Destroy 10 years after approval decision made.~~		
	b. Microfiche Copies Transfer to FRC 5 years after final action. Destroy 20 years after ~~approval decision is made.~~ final action.		
K-24	Medical Device Advisory Committee Records Verbatim transcripts, minutes of meetings, and report on meetings used to document committee activities and recommendations regarding the safety and efficacy of various devices under Section 513 and 515 of the MDAs. Also, general, related correspondence pertaining to the committees. Arranged by Panel name, thereunder chronologically. Vol. on Hand = 21 cu. ft. Annual Acc = 5 cu. ft.	See RCS/B331/52	
Amended by DAlvin, NIR, per Ms. Querre 31 Jan 85	PERMANENT Transfer to FRC 5 years after final transcript is submitted. ~~and is no longer needed for frequent reference.~~ Offer to National Archives 20 years after ~~transfer date.~~ submission in 5 yr. blocks.		
K-25	Device Establishment Registration Registration forms FD 2891 and FD 2891a for all device establishments manufacturing, importing, repacking, relabeling, and distributing medical devices. Used to maintain a reference file on all firms engaged in producing and marketing medical devices. Transfer to FRC 2 years after date of receipt. Destroy 10 years after receipt.		
K-27	Government Wide Quality Assurance Program (GWQAP) Agency evaluations (contractor profiles) of contractors' ability to provide quantities of safe and effective devices before procurement by DOD and other agencies. a. Original (paper) Destroy ~~[illegible]~~ after reproduced on microfilm and verified. b. Microfilm Destroy 10 years after completion of evaluation.		

7. ITEM NO	8. DESCRIPTION OF ITEM (With Inclusive Dates or Retention Periods)	9. SAMPLE OR JOB NO	10. ACTION TAKEN
K-28	Hospital Experience Reporting System (HERS) (ADP) Computer media file containing data on the nature and causes of injuries resulting from the use of devices and other products under FDA jurisdiction. Used to determine which products are especially dangerous and therefore need to be given special attention. Replaced the MODS file (item D-41) in 1979. Destroy (erase) or update individual data elements as needed, not to exceed 8 years from date of entry.	RLS/80771/ D 41	
K-29	Medical Devise Listing Device listing form FD 2892, Medical Device Listing, with related correspondence received from producers and distributors. File is used to keep an inventory of regulated medical devices. Transfer to FRC 6 years after receipt. Destroy 10 years after receipt.		